portion of such source code relevant to the creation of episodes of care has been translated into English text and is added to the specification of the present application. In addition, certain text of the originally submitted specification that was cancelled by way of the November 10, 1999 Amendment (First Substitute Specification) has been re-inserted back by this Amendment. No new matter has been added. In view of the extent of the amendments, they are made by a second substitute specification in accordance with Rule 1.121(b)(3). Clean and marked versions of the second substitute specification are submitted herewith and are accompanied by a statement that it contains no new matter. The marked up version of the second substitute specification shows all the changes being made to the specification of record (First Substitute Specification). Also enclosed is an informal copy of a new drawing figure, Fig. 16, to which the source code translation text refers. Support for Fig. 16 is provided by the text that references it and the source code Appendix.

Applicants respectfully traverse the Examiner's rejection of claim 38 under 35 U.S.C. § 112, first and second paragraphs. It is respectfully submitted that the specification contains an ample description of the subject matter claimed in Claim 38 so as to enable one skilled in the art to which it pertains to practice the claimed invention.

Episode Treatment Category

Applicants respectfully submit that the use of the claim term "episode treatment category" is fully supported by the present Application. An "episode treatment category" is a designator for a particular medical diagnosis or condition, e.g., acute bronchitis. Similarly, an Index Code of the present invention identifies a particular general diagnosis. See first substitute specification pg. 30, ln. 14. An episode of care is defined as "all healthcare services provided to a patient for the diagnosis, treatment, and aftercare of a specific medical condition." See first substitute specification pg. 28, lns. 23-24. The process of generating an episode of care for a particular general diagnosis involves processing the records from a patient's history that relate to the Index Code corresponding to such general diagnosis. Such relationship is determined by the index tables. See first substitute specification pg. 28, lns. 11-13.

There are three index tables described in the specification. The Index Detail Table, the Index Table and the Index Global Table. See first substitute specification pgs. 10-13. The tables in the present application are shown using a conventional relational data base compressed notation that shows the record layout of the table. Referring specifically to the Index Detail Table, as one familiar with relational databases would realize, for a given Index Code (shown in the first line of the table) there will correspond ranges of ICD-9 codes (the beginning and end of each such range being designated by the Beg-ICD and End-ICD entries in table) for each Indicator value. Thus, for a given Index Code and an Indicator value of "I," there will be a range of ICD-9 codes specified in the Index Detail Table, and for the same Index Code and an Indicator value of "R" or "C" there will be other ranges of ICD-9 codes that are specified as corresponding to such Index Code. The search for an episode of care is keyed off the Index Code field. See first substitute specification pg. 10, lns. 28-29.

As explained in the translation of the source code from the Microfiche Appendix, in order for an episode of care to be generated for a medical condition corresponding to a selected Index Code, the patient's history must include records containing occurrences of one or more ICD-9 codes that fall in the range of ICD-9 codes specified in the Index Detail Table for such Index Code having an Indicator value of "I" or "MI." The ICD-9 codes having an Indicator value of "I" or "MI" for a given Index Code are the ICD-9 codes that identify a diagnosis that, in turn, identifies the particular medical condition specified by such Index Code. Such ICD-9 codes are sometimes referred to as "driving diagnoses."

The present invention uses Index Codes for the same reason that the Dang 5,835,897 ("Dang") uses Episode Treatment Groups (ETG's), i.e., to group diagnosis codes entered by a doctor on a medical claim form, or other record being used to create episodes of care, into a smaller number of categories that can be considered equivalent for episode of care purposes. See Dang col. 9, lns. 29-54. The term "episode treatment category" is not used in the Dang specification; it appears only in the claims. Dang claim 3 specifies that each "episode treatment group" is defined by an "episode treatment category," and no different meaning is suggested. Thus, it appears that the two terms are

equivalent, and the Index Code of the present invention exactly corresponds to either of them.

The description of the Examiner's understanding of the subject matter disclosed in the Dang patent and the present application that the Examiner sent with the Interview Summary that was mailed on January 4, 2002 might suggest that Dang's ETG's gather patient records into episodes of care (See lines 4 and 5 of the Dang description.). If this is the case, it is respectfully submitted that such an understanding is incorrect. As is explained in Column 9, lines 20-45 of Dang, ETG's merely classify individual patient records by diagnosis group. The assignment of records relating to an ETG to episodes of care is a separate function.

Grouping Validated Data Records
To Episode Treatment Category

The Examiner states in the Office Action that it is unclear to him that the steps of grouping validated data records to an episode treatment category having a dynamic time window are disclosed in the present application. The Examiner's statement raises two issues: (1) whether the present application supports the claim limitation or grouping validated patient records to an episode treatment category, and (2) whether it supports the claim limitation that the episode treatment category has a dynamic time window associated with it. This portion of these Remarks deals with the first issue.

The manner in which the present invention groups validated patient records to an episode treatment category is described in the first substitute specification at page 30, and, in more detail, in the translation of the source code of the Microfiche Appendix. As explained in section (a) of the translation of the source code, the Index Detail Table is used to build a temporary table, the **tmp_index** file, containing all of the ICD-9 codes and corresponding Indicator values that can be grouped to an episode of care for a given medical condition identified by the selected Index Code.

Next, as described in section (b) of the translation, all patient records are searched to find ICD-9 codes corresponding to those in the **tmp_index** file having an Indicator value of "I" or "MI" for the selected Index Code. A second temporary file is created, **tmp_patient**, listing the identities of all patients whose records include such ICD-9 codes, thereby identifying those patients having records containing a driving diagnosis

for the creation of episodes of care for the selected Index Code. The program next creates a **tmp_data** file and populates it with all claim record lines containing an ICD-9 code listed in the **tmp_index** file for patients identified in the **tmp_patient** file, thereby grouping together all patient records that can be used in generating episodes of care for the selected Index Code. A validation step is performed in the present application during the RAM process that precedes the grouping; that is described at pages 25-29 of the first substitute specification, and particularly at page 26, lines 20-28. Therefore, it is respectfully submitted that the "grouping" claim limitation is clearly supported by the present application.

Dynamic Time Window

Section (f) of the source code translation portion of the second substitute specification describes how the software determines the length of the clear window that is used to separate the records in the **temp_data** file into individual episodes of care for the selected Index Code. Basically, the software acts by linking the Index and Window Tables to determine the clear window period applicable to the selected Index Code for the particular Staging Indicator. For example, a Staging Indicator of "C" designating a chronic condition will normally be associated with a longer clear window than a Staging Indicator of "A" designating an acute condition for the same disease.

A clear window is the "[t]ime period preceding and following an episode of care that must be present without any services provided to the patient relating to the index code or associated codes." See first substitute specification pg. 14 lns. 1-3. Clear window processing defines the onset and resolution points of a diagnosis to establish an episode of care." See first substitute specification pg 30, lns 32-33. A clear window is needed on both ends of an episode of care for it to be valid. See first substitute specification pg 14, lns. 6-22. This language defines clear window as including the beginning window and ending window of an episode of care, during which windows there may not be any services provided to the patient relating to the selected Index Code

The dynamic time window referred to in claim 38 is related to the dynamic nature of the duration of an episode of care. For example, if the clear window time period associated with the Index Code for bronchitis and an "A" (acute) Staging Indicator were

30 days, the drawings below illustrate examples of episodes of care generated from medical claims within a patient medical history for such Index Code.
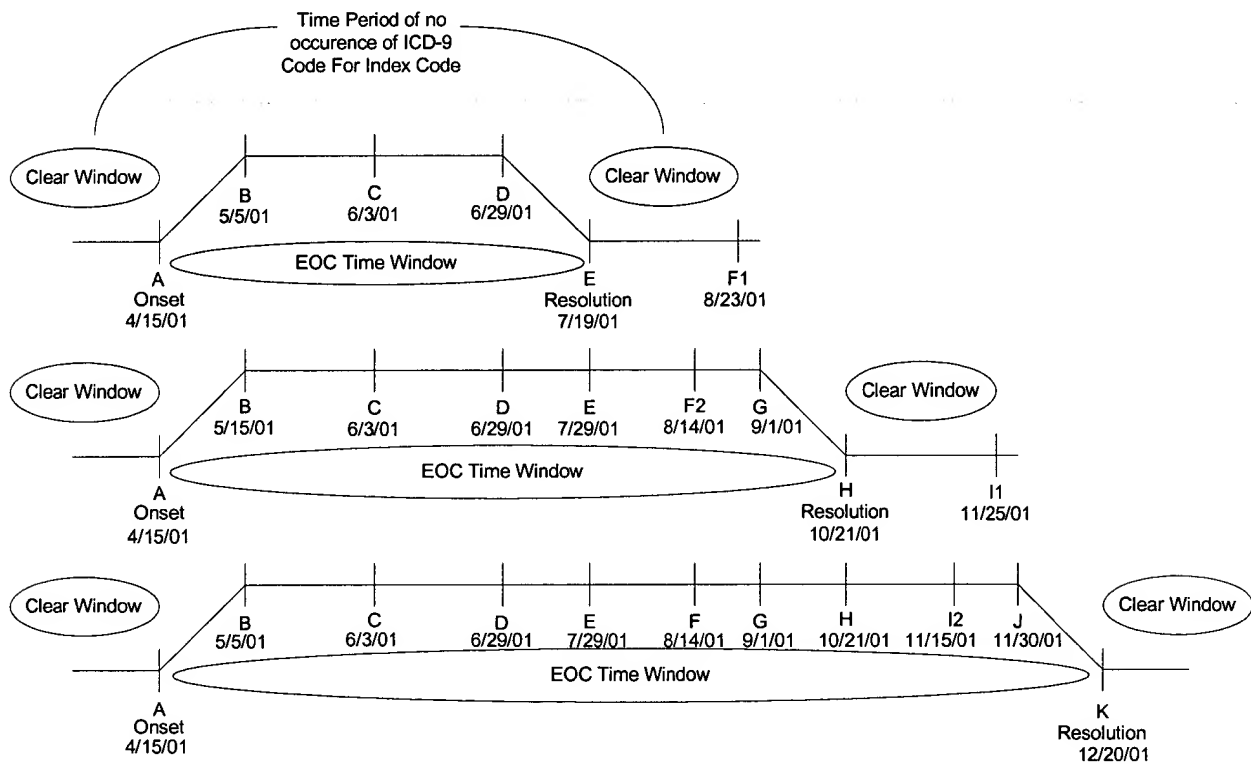
In the above illustrations, the first record in the **temp_data** file containing an ICD-9 code for the patient in question is dated April 15, 2001. Because no other records for such patient exist within the 30-day clear window time period ending April 15, 2001 that contain an ICD-9 code that relates to the Index Code for bronchitis, such date is the onset "A" of a new episode of care for the bronchitis Index Code. The date of medical claim "A" sets a 30-day clear window time period during which patient medical claims related to such Index Code must be located to be grouped into an episode of care with the "A" record. As shown in the first illustration, the search for medical claims related to the selected Index Code in the **temp_data** file, locates medical claims for services performed on: May 5, 2001 "B", June 3, 2001 "C", June 29, 2001 "D", July 19, 2001 "E", and August 23 "F1". As the system scans through the successive records in the **temp_data** file for the patient in question, because the time periods between the successive instances of services for medical claims A, B, C, D and E are all less than the 30-day clear window

time period, the time window encompassed by the episode of care continues to grow through claim E. That is , as the system scans through claims B, C, D and E, the clear window time period is reset at each record for an additional 30-day window until a period of more than 30 days passes without related services being performed. Because there is more than a 30-day time period between services the patient received on July 19, 2001 "E" and August 23, 2001 "F", the episode of care is resolved at "E".

Referring to the second illustration, if medical claim "F" were for services performed on August 14, 2001, the clear window would reset on August 14, 2001 "F" for an additional 30-days because the time period between medical claims "E" and "F" would be less than 30-days. In this case, the episode of care continues for the services received on August 14, 2001 "F2", September 1, 2001 "G", and October 21, 2001 "H". The episode of care is resolved at claim "H" because the 30-day clear window does not reset for claim "I" because the service associated with claim "I" occurred more than 30-days after claim "H". The details of the manner in which the software processes the patient records in the **temp_data** file to group the records into episodes of care are described in section (f) of the source code translation.

As the above illustrations demonstrate, the "episode of care time window" (as opposed to the "clear window") for an Index Code is "dynamic" in the sense that its length depends on whether the patient goes without services related to such Index Code for a period of time longer than the clear window time period for such Index Code and the applicable Staging Indicator.

The episode of care time windows in the present application are "dynamic" in exactly the same way as they are in Dang. The term "dynamic time window" does not appear in the Dang patent specification or in the claims as originally filed. The term was first added to the Dang claim 1 in an Amendment dated July 27,1997 in order to overcome a rejection based on prior art. At pages 15 and 16 of the Amendment, in the Remarks section, Dang explained:

> From this description, it is clear that the GMIS Provider Insight system is nothing more than a "bucketing" system, as more fully described in Applicant's own specification at Pages 9-10. In order to more clearly differentiate the present invention from a "bucketing" system, as described in the GMIS Reference, Applicant has amended independent claim 1 to clarify that "each episode treatment category having a dynamic time

window defining a time period during which validated at least one of a plurality of data records may be compiled to an episode treatment category."...

As clearly described in the GMIS Reference, the GMIS system defines a fixed, static time period, *e.g.*, 42 days, during which related procedures and services may be correlated to the diagnosis or treatment code. When the pre-determined, fixed, static time period expires, the "episode" closes and related interventions are "automatically grouped into a new 'episode.'" In contradistinction, and as amply described in the specification as originally filed, the inventive methodology employs a dynamic time window which changes based upon correlation of other related claim records, until there is an absence of related claim records for a period of time corresponding to the pre-defined time period. Taking, for example, the 42 day duration of care for uncomplicated, community-acquired pneumonia used by GMIS. Where a first record representing a diagnosis and/or treatment of uncomplicated, community-acquired pneumonia is presented, the date of the diagnosis and/or treatment is set as day 1 of the episode. If no other related records are presented, that episode will expire on day 42. However, if a second related record is presented on day 30, the original pre-determined time period of 42 days is reset for an additional 42 day period from day 30, thus effectively enlarging the potential time window for the episode to a total of 72 days. If a third related record is presented on day 45, the inventive method again resets the time window for a period of 42 days from day 45.

As explained at column 6, line 55 through column 7, line 40 of Dang, while processing patient records to generate episodes of care relating to episode treatment groups (ETG's), the program first closes any pending episodes for which a predetermined time period (clear window) has passed, and resets the (clear) time window each time a record matching a current pending episode is processed. This is exactly the same process that is implemented for the present invention, and the "dynamic time window" is associated with the Index Code of the present application in exactly the same manner as it is associated with the episode treatment category of Dang.

In spite of the above clear definition of the meaning of "dynamic time window" in the Dang file history, and in spite of the fact that it couldn't be considered during Reexamination proceedings, Dang submitted information concerning an on sale issue during a recently concluded Reexamination, and argued that his invention was not on sale, based on a new definition of "dynamic time window." Now Dang argued that, to be "dynamic," the episode time window had to include the concept of "shifting," by which,

if, during the generation of an episode of care for one ETG, a record is encountered that changes the appropriate diagnosis to a different ETG, the system can shift the originally assigned ETG to the new one. This belated attempt to change the meaning of a claim term in an issued patent is clearly improper and ineffective.

The need to perform shifting in Dang is an artifact of the manner in which his software operates. In any event, the present application achieves much the same result as "shifting" by a different and simpler route. For example, if, while building an episode of care for the Index Code for bronchitis, the software encounters an ICD-9 code (e.g., for pneumonia) having an Indicator value of "C" (indicating a complication) for the bronchitis Index Code, the records for that patient are excluded from inclusion into the bronchitis episode of care. See First Substitute Specification at page 10 lines 11-12 and line 20, and Page 11 lines 11-12. In effect, the records associated with the patient history are "shifted" out of an episode of care for bronchitis because a "C" Indicator value indicates that there has been a change in condition. When the records are being processed with respect to the Indicator Code for pneumonia, however, the records for bronchitis are recognized as being related conditions for an episode of care for pneumonia and will be included therein, provided the pneumonia clear window criteria are met.

Applicant respectfully submits that, for the reasons set forth above, the subject matter of the invention claimed in Claim 38 is fully supported by the present specification. Applicant also respectfully submits that for the reasons set forth above, Claim 38 is not indefinite and does particularly point out and distinctly claim the subject matter that Applicant regards as the invention
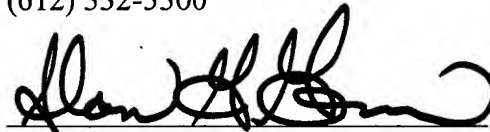
Conclusion

Applicant respectfully thanks the Examiner for taking the time to interview the application and requests reconsideration of the application in view of the above comments. It is particularly important to have the processing of this case proceed as quickly as possible in view of the pending litigation charging the owner of the present application with infringement of the Dang patent, and of the report on the status of this application that must be filed with the Court by February 28, 2002. If the Examiner believes a further telephone

interview of this case would be helpful to expedite examination, contact should be made with the undersigned attorney at (612) 371-5219.

Respectfully submitted,

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Date: January 24, 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SEARE ET AL.	Examiner:	Poinvil
Serial No.:	09/437,567	Group Art Unit:	2755
Filed:	11/10/99	Docket No.:	12344.2USC1
Title:	METHOD AND SYSTEM FOR GENERATING STATISTICALLY-BASED MEDICAL PROVIDER UTILIZATION PROFILES		

CERTIFICATE UNDER 37 CFR 1.6(c): The undersigned hereby certifies that this correspondence is being hand delivered to: Commissioner for Patents, Washington, D.C. 20231, on _1- 25-02_ .

By: _Janice Kent_
Name: _Janice Kent_
         (Bonini + Kent)

Received JAN 25 2002 Technology Center 2100

COMMUNICATION REGARDING REVISED MARKED-UP SUBSTITUTE SPECIFICATION

Box Non-Fee Amendment
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. §1.121(b)(3), Applicants submitted a marked-up version of the second substitute specification. The amendments to the specification include editorial amendments and the addition of a section that includes information set out in the source code contained in the micro fiche appendix to the present application. The source code appendix amendments, beginning on page 46 and ending on page 63 of the marked-up version of the second substitute specification are self explanatory and include several references to the source code micro fiche appendix.

With respect to the remaining amendments, all of which are editorial in nature, Applicants direct the Examining Attorney to the original application specification as the amendments are simply a reinstatement of matter previously deleted from the original application's specification. Regarding the amendment beginning on the bottom of page 11 and ending on the top of page 12 of the marked-up version of the second substitute specification, Applicants direct the Examining Attorney to page 20, lines 12-18 of the original specification for support. Regarding the amendment illustrated on page 19 of the

marked-up version of the second substitute specification, Applicants direct the Examining Attorney to page 33, line 22 through page 34, line 17 for support. Regarding the amendment beginning on page 20 and ending on the top of page 21, Applicants direct the Examining Attorney to page 37, lines 3-24 of the original specification for support. Regarding the amendment beginning on page 22 and ending on page 23 of the marked-up version of the second substitute specification, Applicants direct the Examining Attorney to page 41, line 1 through page 42, line 11 of the original application specification for support.

Applicants respectfully submit that the amendments on the bottom of page 35 of the marked-up version of the second substitute specification are clerical in nature and therefore do not require support. Regarding the amendments illustrated on page 36 of the marked-up version of the second substitute specification, Applicants direct the Examining Attorney to page 65, line 23 through page 66, line 1 of the original application specification for support.

Any questions concerning this matter in its entirety or the marked-up version of the second substitute specification should be directed to the undersigned at 612.371.5219.

Respectfully submitted,

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